

US3402042 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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US3402042

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

[Participant ID](#)

US3402042

[mRNA-1273-P301 Completion Guidelines](#)

US3402042

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3402042

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:44:14

Generated On: 09 Jun 2021 17:24:35

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 16:44:14

Generated On: 09 Jun 2021 17:24:35

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:44:14

Generated On: 09 Jun 2021 17:24:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	DEEP VEIN THROMBOSIS, RIGHT LEG
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	UTICARIA
Start date (dd MMM yyyy)	UN UNK 1967
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	PNEUMONIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:44:18

Generated On: 09 Jun 2021 17:24:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 09:30
Height (<i>xxx.x</i>)	165 cm
Weight (<i>xxx.x</i>)	60.8 kg
BMI (<i>xxx.x</i>)	22.33242 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:44:18

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:44:18

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:44:18

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 184073

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒ No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Height	ND - Not Done
Weight	ND - Not Done

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 09:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 11:28
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 JUL 2020

What was the treatment time? (00:00-23:59) 10:56 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 10:56

Which arm was used to give treatment? Left Arm ☐
Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JUL 2020
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	28 JUL 2020 10:32

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Collection date (dd MMM yyyy)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:22	28 JUL 2020 10:22
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

28 JUL 2020 11:36

PC Open Date & Time

28 JUL 2020 11:16

PC Close Date & Time

28 JUL 2020 13:46

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	28 JUL 2020 14:54
PC Open Date & Time	28 JUL 2020 14:41
PC Close Date & Time	29 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

29 JUL 2020 13:13

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 JUL 2020 12:29

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 JUL 2020 12:14

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

01 AUG 2020 12:08

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

02 AUG 2020 20:50

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

03 AUG 2020 12:07

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 11:36

PC Open Date & Time

28 JUL 2020 11:16

PC Close Date & Time

28 JUL 2020 13:46

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

20

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 15:01

PC Open Date & Time

28 JUL 2020 14:41

PC Close Date & Time

29 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

500

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 13:14

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

200

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 12:30

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 12:14

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 12:09

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 20:51

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:08

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 11:37
PC Open Date & Time	28 JUL 2020 11:16
PC Close Date & Time	28 JUL 2020 13:46

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 15:02
PC Open Date & Time	28 JUL 2020 14:41
PC Close Date & Time	29 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 13:15
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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EAB) (1725)

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US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 12:31
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 12:15
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:10
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 20:51
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

62 of 2595

EAB) (1725)

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 12:08
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:44
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 25 AUG 2020

What was the treatment time? (00:00-23:59) 10:14 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 10:14

Which arm was used to give treatment? Left Arm ☐
Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	09:47 (24 HR)
Collection date and time (derived)	25 AUG 2020 09:47

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	25 AUG 2020 09:50
Nasopharyngeal Swab 2	No		

US3402042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

25 AUG 2020 10:47

PC Open Date & Time

25 AUG 2020 10:34

PC Close Date & Time

25 AUG 2020 13:04

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

99.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐
No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	25 AUG 2020 16:51
PC Open Date & Time	25 AUG 2020 13:59
PC Close Date & Time	26 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

26 AUG 2020 12:11

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

27 AUG 2020 12:25

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

28 AUG 2020 15:19

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

29 AUG 2020 12:06

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 AUG 2020 15:32

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

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If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 AUG 2020 12:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 10:47

PC Open Date & Time

25 AUG 2020 10:34

PC Close Date & Time

25 AUG 2020 13:04

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 16:52

PC Open Date & Time

25 AUG 2020 13:59

PC Close Date & Time

26 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:12

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:26

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 15:19

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:06

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 15:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 10:48
PC Open Date & Time	25 AUG 2020 10:34
PC Close Date & Time	25 AUG 2020 13:04

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 16:53
PC Open Date & Time	25 AUG 2020 13:59
PC Close Date & Time	26 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:13
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:27
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 15:20
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:07
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 15:33
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:05
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	09:12 (24 HR)
Collection date and time (derived)	24 SEP 2020 09:12

US3402042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:34:57

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 SEP 2020 10:49:50
Patient Cloud Open Date & Time	27 SEP 2020 00:01
Patient Cloud Close Date & Time	01 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 OCT 2020 11:27:56
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 OCT 2020 16:39:12
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 OCT 2020 22:23:08
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 19:05:22
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 106

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

08 NOV 2020 22:07:41

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 113

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 NOV 2020 22:38:51

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 NOV 2020 10:08:55

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 09:21:41
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

04 DEC 2020 08:58:02

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 DEC 2020 09:06:28

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 DEC 2020 08:26:29

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 DEC 2020 08:41:42

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 DEC 2020 08:08:08

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

07 JAN 2021 08:50:27

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 JAN 2021 08:39:04

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 09:59:14
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 07:59:03
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 10:32:01
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 09:18:32
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 10:29:25
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 FEB 2021 07:31:42

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 13:15:24
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 08:31:35
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 09:11:40
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 MAR 2021 09:29:45

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 07:20:55
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

08 APR 2021 08:45:23

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 APR 2021 10:12:45

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 APR 2021 11:31:44

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

29 APR 2021 08:38:22

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	22 SEP 2022 00:01
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Patient Cloud Close Date & Time	26 SEP 2022 23:59
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US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3402042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:24:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 01:34:27

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:11:09

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:11:09

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	18 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:22:33

Generated On: 09 Jun 2021 17:24:35

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3402042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 FEB 2021
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	18 FEB 2021 12:57

US3402042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Date of Contact	12 OCT 2020
Time of Contact	14:00
Date and Time of Contact (derived)	12 OCT 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	04 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (8)

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	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (9)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (10)

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Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	90 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Date of Visit	12 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	12 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:19 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 14:19
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3402042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 OCT 2020

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	21 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Date of updated informed consent (dd MMM yyyy) 06 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	13:49 (24 HR)
Collection date and time (derived)	21 JAN 2021 13:49

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	13:50
Collection Date and Time (derived)	21 JAN 2021 13:50

US3402042

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:30:01

Generated On: 09 Jun 2021 17:24:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:30:01

Generated On: 09 Jun 2021 17:24:35

AEID	USA-US059-2020-MRNA-1273-P30 1000006
Adverse event	WORSENING OF EMPHYSEMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	17 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:30:01

Generated On: 09 Jun 2021 17:24:35

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:30:01

Generated On: 09 Jun 2021 17:24:35

SUBJECT BEGAN WITH
CONGESTION 01OCT2020 WENT
TO HIS PULMONOLOGIST AND
WAS STARTED ON
PREDNISONE AND CEFDIR.
SUBJECT CAME FOR ILLNESS
VISIT 12OCT2020. AFTER
HAVING PHYSICAL EXAM IT
WAS DETERMINED BY SUB
INVESTIGATOR THAT SUBJECT
SHOULD GO THE THE
EMERGENCY ROOM FOR
FURTHER EVALUATION.
SUBJECT WAS LATER
ADMITTED TO HOSPITAL FOR
FURTHER TREATMENT. SUBJCT
HAD CHEST XRAY WHICH
SHOWED CHANGES IN BTH
LUNGS PARTICULARLY WITH
IN THE UPPER LOBES WITH
LINEAR SCARRING WITH IN
THE MID AND LOWER LUNG
ZONES AS NOTED ON PREIOUS
STUDIES. SUBJECT IS ON 3L OF
OXYGEN BY NASAL CANNULA.
SUBJECT WILL CONTINUE ON
CEFTRIAXONE, AND
AZITHROMYCIN,. WILL BE
STARTED ON
METHYLPREDNISOLONE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication DEEP VEIN THROMBOSIS/
PULMINARY EMBOLISM

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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Name of Medication TOMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERTROPHY

Dose per administration .04

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1992	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication BISOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication HYDROCHLORATHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication ROFLUMILAST

Prophylaxis Yes ☐
No ☒

Indication EMPHYSEMA

Dose per administration 250

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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Name of Medication BEVESPI AEROSPHERE

Prophylaxis Yes ☐
No ☒

Indication EMPHYSEMA

Dose per administration 9/4.8

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF EMPHYSEMA

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF EMPHYSEMA

Dose per administration 30

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:21:18

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF EMPHYSEMA

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication PREDNISONEE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF EMPHYSEMA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF EMPHYSEMA

Dose per administration 15

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING EMPHYSEMA

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING EMPHYSEMA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☒
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING EMPHYSEMA

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING EMPHYSEMA

Dose per administration 3

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify LITERS

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING EMPHYSEMA

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:21:18

Generated On: 09 Jun 2021 17:24:35

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
12 OCT 2020	CHEST XRAY	Adverse Event	

US3402042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:24:35

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3402042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:24:35

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/OCT/2020 16:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/OCT/2020 15:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 01:22:32

Generated On: 09 Jun 2021 17:24:35

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/NOV/2020 14:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3402042 (Prod: Meridian Clinical Research, LLC)

US3402042

Form: Participant Creation

Generated On: 09 Jun 2021 17:24:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'US3402042'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:22

US3402042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 15:05:34
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:23

US3402042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:05:34

US3402042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'SCRN'	System	28 Jul 2020 15:05:34

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:24

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '72'	(b) (4)	28 Jul 2020 15:06:06
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'YEARS'	System	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '72'	System	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'Male (M)'	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'I'	(b) (4)	28 Jul 2020 15:06:06
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	(b) (4)	28 Jul 2020 15:06:06
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	(b) (4)	28 Jul 2020 15:06:06
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	Tarin Gordon (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	(b) (4)	28 Jul 2020 15:06:06
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered empty.	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	(b) (4)	28 Jul 2020 15:06:06
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:35

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '0'	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered '28 Jul 2020'	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jul 2020'	System	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2020'	System	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'Amendment 1 (1)'	(b) (4) Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 15:06:23
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered empty.	(b) (4) Tarin Gordon (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered empty.	(b) (4)	28 Jul 2020 15:06:23
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	28 Jul 2020 15:06:23
	(b) (4)	

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'I'	System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:24:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:14
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 15:06:31
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:24:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:24:24
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH #7 PULMONARY HYPERTENSION (UN UNK 2000-Ongoing). If yes, please ensure only one entry is recorded. Otherwise, please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 10:17:51
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH #7 PULMONARY HYPERTENSION (UN UNK 2000-Ongoing). If yes, please ensure only one entry is recorded. Otherwise, please clarify.' answered with 'THIS IS OT PULMONARY HYPERTENSION' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:12:30
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH #7 PULMONARY HYPERTENSION (UN UNK 2000-Ongoing). If yes, please ensure only one entry is recorded. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:05:45
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:34
Data point term sent to Coder	System	29 Jul 2020 13:27:45
User entered 'HYPERTENSION'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2000'	Tarin Gordon (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:27:13
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2000'	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2000'	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:30
Data point term sent to Coder	System	29 Jul 2020 13:27:46
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Tarin Gordon (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 1992'	Tarin Gordon (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:27:44
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 1992'	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '1992'	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:40
Data point term sent to Coder	System	29 Jul 2020 13:41:53
User entered 'PULMONARY EMBOLISM'	Tarin Gordon (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2018'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:41:28
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:41:28
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2018'	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2018'	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 21:57:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 21:57:11
Data point term sent to Coder	System	29 Jul 2020 13:42:55
User entered 'DEEP VEIN THROMBOSIS, RIGHT LEG'	Tarin Gordon (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2018'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:42:07
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:42:07
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2018'	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2018'	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 12:31:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 12:31:14
Data point term sent to Coder	System	03 Aug 2020 21:50:52
Datapoint queued for coding (5007943).	System	03 Aug 2020 21:49:54
User entered 'URTICARIA' reason for change: Data Entry Error	Tarin Gordon (b) (4)	29 Jul 2020 13:43:02
Data point term sent to Coder	System	29 Jul 2020 13:42:55
User entered 'URTICARIA'	Tarin Gordon (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 1967'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:42:41
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:42:41
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:42:41
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 1967'	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '1967'	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 21:40:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:41
Data point term sent to Coder	System	29 Jul 2020 13:43:55
User entered 'PNEUMONIA'	Tarin Gordon (b) (4)	29 Jul 2020 13:43:23
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2016'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:43:23
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4)	29 Jul 2020 13:43:23
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2016'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:43:23
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 21:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:30
Data point term sent to Coder	System	29 Jul 2020 13:44:56
User entered 'HIATAL HERNIA'	Tarin Gordon (b) (4)	29 Jul 2020 13:44:02
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 1990'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:44:02
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:44:02
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:44:02
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 1990'	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '1990'	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:41:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:41:04
Data point term sent to Coder	System	29 Jul 2020 13:44:58
User entered 'DEPRESSION'	Tarin Gordon (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2010'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:44:17
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2010'	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2010'	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:39
Data point term sent to Coder	System	29 Jul 2020 13:44:58
User entered 'IRRITABLE BOWEL SYNDROME'	Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2010'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2010'	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2010'	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:48:25
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:58:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:06:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:25
Data point term sent to Coder	System	29 Jul 2020 13:50:04
User entered 'EMPHYSEMA'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 2000'	Tarin Gordon (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:49:32
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:49:32
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:49:32
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:49:32
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 2000'	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '2000'	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:04:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:04:07
Data point term sent to Coder	System	05 Oct 2020 16:02:52
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Traci Hull (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'UN UNK 1990'	Traci Hull (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Traci Hull (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	Traci Hull (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	05 Oct 2020 16:02:13
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'Jan 1990'	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '1990'	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:24:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered empty.	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:50:39
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '28 Jul 2020'	(b) (4)	29 Jul 2020 13:50:39
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '09:30'	(b) (4)	29 Jul 2020 13:50:39
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '28 Jul 2020 09:30'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '165' cm	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
DataPoint set to visible.	(b) (4) System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '60.8' kg	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
DataPoint set to visible.	(b) (4) System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
Amendment Manager: User entered '22.33242'	System	16 Sep 2020 23:37:15
User entered '22.3'	System	29 Jul 2020 13:50:39
DataPoint set to visible.	System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'kg/m2'	System	29 Jul 2020 13:50:39
DataPoint set to visible.	System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:48:14
User entered '36.7' C	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:48:14
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	29 Jul 2020 13:50:39
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:50:39
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:48:14
User entered '66'	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'bpm'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:48:14
User entered '16'	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'breaths/min'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:48:14
User entered '108'	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'mmHg'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:48:14
User entered '64'	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
	(b) (4)	

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'mmHg'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33

US3402042

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:50:46
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 13:12:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 15:23:19
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:46

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:35

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'No (N)'	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:51:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered '0'	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:44:18
User entered empty.	(b) (4)	29 Jul 2020 13:51:17
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:51:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:51:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:31

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'VISIT1'	System	29 Jul 2020 13:51:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:35

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:26

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:06:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:06:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 14:04:26
User entered '184073' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:26

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 14:04:26

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Folder: Visit 1 Day 1

Form: Randomization

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Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:59

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:59

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:35

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:51:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:51:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 13:51:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:47:52
User entered '165' cm	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:47:52
User entered '60.8' kg	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:47:52
User entered '165' cm	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:47:52
User entered '60.8' kg	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:53:59
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '09:30'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '28 Jul 2020 09:30'	System	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '36.7' C	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Oral (Oral)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '66'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'bpm'	System	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '16'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'breaths/min'	System	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '108'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '64'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	29 Jul 2020 13:53:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:47:52
User entered '165' cm	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 00:47:52
User entered '60.8' kg	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 18:49:00
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30MIN' (Site from System).	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:54:10
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		29 Jul 2020 13:53:59
User entered '11:28'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '28 Jul 2020 11:28'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '97.1' F	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '68'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'bpm'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '16'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'breaths/min'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '106'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '68'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 13:56:39

US3402042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 13:56:39

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 15:07:15
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	28 Jul 2020 15:07:15
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Tarin Gordon (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '10:56'	(b) (4)	28 Jul 2020 15:07:15
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '28 Jul 2020 10:56'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Right Arm (RIGHT ARM)'	Tarin Gordon (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'ONCE'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:57:01
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:57:01
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '10:32'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:57:01
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '28 Jul 2020 10:32'	System	29 Jul 2020 13:57:01

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '28 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '10:22'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '28 Jul 2020 10:22'	System	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:57:28
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	29 Jul 2020 13:57:28
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	29 Jul 2020 13:57:28
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	29 Jul 2020 13:57:18
User entered empty.	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered empty.	System	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 13:57:41
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	29 Jul 2020 13:57:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:35:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered 'Yes (Y)'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:35:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7' User entered '97.1'	System	28 Jul 2020 15:36:14
	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered 'No (N)'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered '28 Jul 2020 11:36'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 11:16'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 13:46'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:53:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba' User entered 'Yes (Y)'	System	28 Jul 2020 18:54:09
	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:53:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba' User entered '97.3'	System	28 Jul 2020 18:54:09
	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:53:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba' User entered 'No (N)'	System	28 Jul 2020 18:54:09
	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:54:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba' User entered '28 Jul 2020 14:54'	System	28 Jul 2020 18:54:09
	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 14:41'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 2'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:12:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25'	System	29 Jul 2020 17:13:25
User entered 'Yes (Y)'	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25' User entered '98.3'	System	29 Jul 2020 17:13:25
	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25'	System	29 Jul 2020 17:13:25
User entered 'No (N)'	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25' User entered '29 Jul 2020 13:13'	System	29 Jul 2020 17:13:25
	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 3'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411' User entered 'Yes (Y)'	System	30 Jul 2020 16:29:41
	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411' User entered '97.3'	System	30 Jul 2020 16:29:41
	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411' User entered 'No (N)'	System	30 Jul 2020 16:29:41
	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411' User entered '30 Jul 2020 12:29'	System	30 Jul 2020 16:29:41
	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 4'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered 'Yes (Y)'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered '97.0'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered 'No (N)'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447' User entered '31 Jul 2020 12:14'	System	31 Jul 2020 16:14:24
	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 5'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d' User entered 'Yes (Y)'	System	01 Aug 2020 16:08:51
	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d' User entered '97.3'	System	01 Aug 2020 16:08:51
	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d'	System	01 Aug 2020 16:08:51
User entered 'No (N)'	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d'	System	01 Aug 2020 16:08:51
User entered '01 Aug 2020 12:08'	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 6'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3' User entered 'Yes (Y)'	System	03 Aug 2020 00:51:00
	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3' User entered '97.3'	System	03 Aug 2020 00:51:00
	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3'	System	03 Aug 2020 00:51:00
User entered 'No (N)'	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3'	System	03 Aug 2020 00:51:00
User entered '02 Aug 2020 20:50'	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 7'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78' User entered 'Yes (Y)'	System	03 Aug 2020 16:07:49
	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78' User entered '97.4'	System	03 Aug 2020 16:07:49
	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78'	System	03 Aug 2020 16:07:49
User entered 'No (N)'	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78' User entered '03 Aug 2020 12:07'	System	03 Aug 2020 16:07:49
	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered 'None (1)'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:34', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d' User entered 'No (N)'	System	28 Jul 2020 15:36:51
	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d' User entered 'No (N)'	System	28 Jul 2020 15:36:51
	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:44', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered 'None (1)'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d' User entered '28 Jul 2020 11:36'	System	28 Jul 2020 15:36:51
	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 11:16'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 13:46'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:54:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:54:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265' User entered 'No (N)'	System	28 Jul 2020 19:01:53
	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:58:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265' User entered 'Yes (Y)'	System	28 Jul 2020 19:01:53
	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:01:43', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265' User entered '20'	System	28 Jul 2020 19:01:53
	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:59:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered 'None (1)'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:01:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265' User entered '28 Jul 2020 15:01'	System	28 Jul 2020 19:01:53
	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 14:41'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 2'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'No (N)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'Yes (Y)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54' User entered '500'	System	29 Jul 2020 17:14:33
	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'None (1)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54' User entered '29 Jul 2020 13:14'	System	29 Jul 2020 17:14:33
	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 3'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d'	System	30 Jul 2020 16:30:20
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d' User entered 'No (N)'	System	30 Jul 2020 16:30:20
	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d' User entered 'Yes (Y)'	System	30 Jul 2020 16:30:20
	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d' User entered '200'	System	30 Jul 2020 16:30:20
	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d' User entered 'None (1)'	System	30 Jul 2020 16:30:20
	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d' User entered '30 Jul 2020 12:30'	System	30 Jul 2020 16:30:20
	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 4'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f' User entered 'None (1)'	System	31 Jul 2020 16:14:47
	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f' User entered 'No (N)'	System	31 Jul 2020 16:14:47
	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f' User entered 'No (N)'	System	31 Jul 2020 16:14:47
	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f' User entered 'None (1)'	System	31 Jul 2020 16:14:47
	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f' User entered '31 Jul 2020 12:14'	System	31 Jul 2020 16:14:47
	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 5'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered 'None (1)'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964' User entered 'No (N)'	System	01 Aug 2020 16:09:23
	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964' User entered 'No (N)'	System	01 Aug 2020 16:09:23
	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered 'None (1)'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964' User entered '01 Aug 2020 12:09'	System	01 Aug 2020 16:09:23
	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 6'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'None (1)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:09', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'No (N)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9' User entered 'No (N)'	System	03 Aug 2020 00:51:23
	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'None (1)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9' User entered '02 Aug 2020 20:51'	System	03 Aug 2020 00:51:23
	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 7'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'None (1)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'No (N)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'No (N)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'None (1)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered '03 Aug 2020 12:08'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'None (0)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'None (0)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'None (0)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'None (0)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'None (0)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'None (0)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:24', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered 'No (N)'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6' User entered '28 Jul 2020 11:37'	System	28 Jul 2020 15:37:32
	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 11:16'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 13:46'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:01:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'None (0)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'No interference with activity (1)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'None (0)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:12', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'None (0)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'None (0)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'None (0)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered 'No (N)'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d' User entered '28 Jul 2020 15:02'	System	28 Jul 2020 19:02:29
	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Jul 2020 14:41'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 2'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500' User entered 'None (0)'	System	29 Jul 2020 17:15:20
	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500' User entered 'None (0)'	System	29 Jul 2020 17:15:20
	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500' User entered 'None (0)'	System	29 Jul 2020 17:15:20
	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:15:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:15:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500' User entered 'No (N)'	System	29 Jul 2020 17:15:20
	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:15:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500' User entered '29 Jul 2020 13:15'	System	29 Jul 2020 17:15:20
	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 3'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'None (0)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'None (0)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'None (0)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'None (0)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'None (0)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'None (0)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:31:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered 'No (N)'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:31:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083' User entered '30 Jul 2020 12:31'	System	30 Jul 2020 16:31:06
	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 4'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'None (0)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'None (0)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'None (0)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'None (0)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'None (0)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'None (0)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered 'No (N)'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered '31 Jul 2020 12:15'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 5'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a' User entered 'None (0)'	System	01 Aug 2020 16:10:05
	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'Significant; prevents daily activity (3)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'Some interference with activity (2)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a' User entered 'None (0)'	System	01 Aug 2020 16:10:05
	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a' User entered 'None (0)'	System	01 Aug 2020 16:10:05
	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a' User entered 'None (0)'	System	01 Aug 2020 16:10:05
	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:10:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'No (N)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:10:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered '01 Aug 2020 12:10'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 6'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered 'None (0)'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered 'None (0)'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered 'None (0)'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered 'None (0)'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered 'None (0)'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered 'None (0)'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'No (N)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9' User entered '02 Aug 2020 20:51'	System	03 Aug 2020 00:51:57
	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 7'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42' User entered 'None (0)'	System	03 Aug 2020 16:08:40
	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42' User entered 'None (0)'	System	03 Aug 2020 16:08:40
	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42' User entered 'None (0)'	System	03 Aug 2020 16:08:40
	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42' User entered 'None (0)'	System	03 Aug 2020 16:08:40
	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42' User entered 'None (0)'	System	03 Aug 2020 16:08:40
	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42' User entered 'None (0)'	System	03 Aug 2020 16:08:40
	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'No (N)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered '03 Aug 2020 12:08'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '04 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:09:44
User entered '4 Aug 2020'	Traci Hull (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Traci Hull (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	11 Aug 2020 18:34:45
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	11 Aug 2020 18:34:45

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '11 Aug 2020'	Traci Hull (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Traci Hull (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	Traci Hull (b) (4)	11 Aug 2020 18:35:11

US3402042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	11 Aug 2020 18:35:11

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	19 Aug 2020 12:16:53
	(b) (4)	

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '18 Aug 2020'	Traci Hull (b) (4)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Traci Hull (b) (4)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 12:48:08
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 12:48:04
User entered 'Yes (Y)'	Traci Hull (b) (4)	19 Aug 2020 12:17:03

US3402042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '1'	System	26 Aug 2020 12:48:08
User entered empty.	System	26 Aug 2020 12:48:04
User entered '1'	System	19 Aug 2020 12:17:03

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	(b) (4)	
	Traci Hull (b) (4)	25 Aug 2020 15:23:19
	(b) (4)	

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'VISIT2'	System	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '09:10'	(b) (4)	
	Traci Hull (b) (4)	25 Aug 2020 15:24:32
	(b) (4)	

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '25 Aug 2020 09:10'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '36.6' C	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '70'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'bpm'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '15'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'breaths/min'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '110'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '72'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '10:44'	(b) (4)	25 Aug 2020 15:24:32
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '25 Aug 2020 10:44'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '36.8' C	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '72'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'bpm'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '15'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'breaths/min'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '110'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '72'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	25 Aug 2020 15:24:40
	(b) (4)	

US3402042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	(b) (4)	
	Traci Hull (b) (4)	25 Aug 2020 15:24:40
	(b) (4)	

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Abigail Wine (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4) Abigail Wine (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Abigail Wine (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	(b) (4) Abigail Wine (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '10:14'	(b) (4) Abigail Wine (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '25 Aug 2020 10:14'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Right Arm (RIGHT ARM)'	Abigail Wine (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'ONCE'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '09:47'	(b) (4)	
	Traci Hull (b) (4)	25 Aug 2020 15:24:59
	(b) (4)	

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '25 Aug 2020 09:47'	System	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '25 Aug 2020'	Traci Hull (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '09:50'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '25 Aug 2020 09:50'	System	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered empty.	System	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 15:25:05

US3402042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	25 Aug 2020 15:25:05

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:46:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0' User entered 'Yes (Y)'	System	25 Aug 2020 14:47:19
	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:46:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0' User entered '97.7'	System	25 Aug 2020 14:47:19
	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0' User entered 'No (N)'	System	25 Aug 2020 14:47:19
	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0' User entered '25 Aug 2020 10:47'	System	25 Aug 2020 14:47:19
	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 10:34'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 13:04'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:34', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1' User entered 'Yes (Y)'	System	25 Aug 2020 20:51:59
	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1' User entered '99.5'	System	25 Aug 2020 20:51:59
	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1'	System	25 Aug 2020 20:51:59
User entered 'No (N)'	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1' User entered '25 Aug 2020 16:51'	System	25 Aug 2020 20:51:59
	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 13:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 2'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d' User entered 'Yes (Y)'	System	26 Aug 2020 16:11:55
	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d' User entered '95.9'	System	26 Aug 2020 16:11:55
	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d' User entered 'No (N)'	System	26 Aug 2020 16:11:55
	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d' User entered '26 Aug 2020 12:11'	System	26 Aug 2020 16:11:55
	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 3'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037' User entered 'Yes (Y)'	System	27 Aug 2020 16:25:42
	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037' User entered '97.6'	System	27 Aug 2020 16:25:42
	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:34', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037'	System	27 Aug 2020 16:25:42
User entered 'No (N)'	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037' User entered '27 Aug 2020 12:25'	System	27 Aug 2020 16:25:42
	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 4'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6' User entered 'Yes (Y)'	System	28 Aug 2020 19:19:30
	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6' User entered '97.2'	System	28 Aug 2020 19:19:30
	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6' User entered 'No (N)'	System	28 Aug 2020 19:19:30
	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6' User entered '28 Aug 2020 15:19'	System	28 Aug 2020 19:19:30
	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 5'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903' User entered 'Yes (Y)'	System	29 Aug 2020 16:06:23
	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903' User entered '97.2'	System	29 Aug 2020 16:06:23
	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903'	System	29 Aug 2020 16:06:23
User entered 'No (N)'	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903'	System	29 Aug 2020 16:06:23
User entered '29 Aug 2020 12:06'	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 6'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a' User entered 'Yes (Y)'	System	30 Aug 2020 19:32:48
	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a' User entered '97.5'	System	30 Aug 2020 19:32:48
	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a' User entered 'No (N)'	System	30 Aug 2020 19:32:48
	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a' User entered '30 Aug 2020 15:32'	System	30 Aug 2020 19:32:48
	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 7'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:02:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623' User entered 'Yes (Y)'	System	31 Aug 2020 16:04:19
	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623' User entered '97.6'	System	31 Aug 2020 16:04:19
	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:10', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623'	System	31 Aug 2020 16:04:19
User entered 'No (N)'	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623'	System	31 Aug 2020 16:04:19
User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea' User entered 'None (1)'	System	25 Aug 2020 14:47:49
	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea' User entered 'No (N)'	System	25 Aug 2020 14:47:49
	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea' User entered 'No (N)'	System	25 Aug 2020 14:47:49
	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea' User entered 'None (1)'	System	25 Aug 2020 14:47:49
	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea' User entered '25 Aug 2020 10:47'	System	25 Aug 2020 14:47:49
	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 10:34'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 13:04'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:10', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'No (N)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'No (N)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'None (1)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb' User entered '25 Aug 2020 16:52'	System	25 Aug 2020 20:52:37
	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 13:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 2'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered 'No (N)'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061' User entered 'No (N)'	System	26 Aug 2020 16:12:37
	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061' User entered 'None (1)'	System	26 Aug 2020 16:12:37
	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061' User entered '26 Aug 2020 12:12'	System	26 Aug 2020 16:12:37
	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 3'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'No (N)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37' User entered 'No (N)'	System	27 Aug 2020 16:26:25
	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'None (1)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered '27 Aug 2020 12:26'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 4'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5' User entered 'None (1)'	System	28 Aug 2020 19:19:57
	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5' User entered 'No (N)'	System	28 Aug 2020 19:19:57
	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5' User entered 'No (N)'	System	28 Aug 2020 19:19:57
	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5' User entered 'None (1)'	System	28 Aug 2020 19:19:57
	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5' User entered '28 Aug 2020 15:19'	System	28 Aug 2020 19:19:57
	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 5'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc' User entered 'None (1)'	System	29 Aug 2020 16:06:49
	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc' User entered 'No (N)'	System	29 Aug 2020 16:06:49
	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc' User entered 'No (N)'	System	29 Aug 2020 16:06:49
	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:43', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc' User entered 'None (1)'	System	29 Aug 2020 16:06:49
	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc' User entered '29 Aug 2020 12:06'	System	29 Aug 2020 16:06:49
	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 6'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'None (1)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'No (N)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339' User entered 'No (N)'	System	30 Aug 2020 19:33:07
	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'None (1)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339' User entered '30 Aug 2020 15:33'	System	30 Aug 2020 19:33:07
	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 7'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'None (1)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'No (N)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'No (N)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'None (1)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34' User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:07:12
	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered 'None (0)'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered 'None (0)'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:12', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered 'None (0)'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered 'None (0)'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered 'None (0)'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered 'None (0)'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'No (N)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4' User entered '25 Aug 2020 10:48'	System	25 Aug 2020 14:48:35
	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 10:34'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 13:04'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'None (0)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'None (0)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:43', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'None (0)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'None (0)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'None (0)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'None (0)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered 'No (N)'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:53:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9' User entered '25 Aug 2020 16:53'	System	25 Aug 2020 20:53:05
	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '25 Aug 2020 13:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 2'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered 'None (0)'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered 'None (0)'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered 'None (0)'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered 'None (0)'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:10', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered 'None (0)'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered 'No (N)'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e' User entered '26 Aug 2020 12:13'	System	26 Aug 2020 16:13:24
	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 3'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered 'None (0)'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered 'None (0)'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered 'None (0)'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered 'None (0)'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered 'None (0)'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:27:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered 'No (N)'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:27:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3' User entered '27 Aug 2020 12:27'	System	27 Aug 2020 16:27:08
	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 4'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'No (N)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered '28 Aug 2020 15:20'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 5'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'None (0)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'None (0)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'None (0)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'None (0)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'None (0)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'None (0)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered 'No (N)'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5' User entered '29 Aug 2020 12:07'	System	29 Aug 2020 16:07:23
	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 6'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772' User entered 'None (0)'	System	30 Aug 2020 19:33:43
	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772' User entered 'None (0)'	System	30 Aug 2020 19:33:43
	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772' User entered 'None (0)'	System	30 Aug 2020 19:33:43
	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'No (N)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered '30 Aug 2020 15:33'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 7'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'None (0)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'None (0)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'None (0)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'None (0)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'None (0)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'None (0)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:04:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered 'No (N)'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:04:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e' User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:07:58
	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '01 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:10:39
User entered '1 Sep 2020'	Traci Hull (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Traci Hull (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	Traci Hull (b) (4)	02 Sep 2020 11:19:13

US3402042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	02 Sep 2020 11:19:13

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 14:17:27
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '08 Sep 2020'	(b) (4) Traci Hull (b) (4)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Traci Hull (b) (4)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 14:17:35
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	15 Sep 2020 14:17:35

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 14:17:49
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '15 Sep 2020'	Traci Hull (b) (4)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	Traci Hull (b) (4)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 14:17:52
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	15 Sep 2020 14:17:52

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '24 Sep 2020'	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:11:54
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'VISIT3'	System	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:12:56
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '24 Sep 2020'	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:12:56
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '09:05'	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:12:56
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '24 Sep 2020 09:05'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '36.8' C	Traci Hull (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4) Traci Hull (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '72'	Traci Hull (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'bpm'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '22'	(b) (4) Traci Hull (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'breaths/min'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '130'	Traci Hull (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '78'	Traci Hull (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'mmHg'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49

US3402042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:13:06
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:13:06
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '24 Sep 2020'	(b) (4) Traci Hull (b) (4)	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered '09:12'	(b) (4)	
	Traci Hull (b) (4)	24 Sep 2020 15:13:20
	(b) (4)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered '24 Sep 2020 09:12'	System	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:34:58
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Sep 2020 15:13:24

US3402042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	24 Sep 2020 15:13:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 64'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-09-27T10:49:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b85d03a5-02bf-4703-a88e-3ae5c2e0390c' User entered 'No (N)'	System	27 Sep 2020 14:49:52
	System	27 Sep 2020 14:49:52

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-09-27T10:49:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b85d03a5-02bf-4703-a88e-3ae5c2e0390c'	System	27 Sep 2020 14:49:52
User entered 'No (N)'	System	27 Sep 2020 14:49:52

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-09-27T10:49:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b85d03a5-02bf-4703-a88e-3ae5c2e0390c' User entered '27 Sep 2020 10:49:50'	System	27 Sep 2020 14:49:52
	System	27 Sep 2020 14:49:52

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '27 Sep 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '01 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 71'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:51:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'Yes (Y)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:52:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'No (N)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:52:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'No (N)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:52:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'Yes (Y)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T11:27:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T11:27:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238' User entered '04 Oct 2020 11:27:56'	System	04 Oct 2020 15:28:05
	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '04 Oct 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '08 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 78'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'Yes (Y)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'No (N)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'No (N)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'Yes (Y)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:39:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:39:12', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24' User entered '12 Oct 2020 16:39:12'	System	12 Oct 2020 20:39:23
	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '11 Oct 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '15 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 92'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:22:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c' User entered 'Yes (Y)'	System	26 Oct 2020 02:23:13
	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:22:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered 'No (N)'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:22:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c' User entered 'No (N)'	System	26 Oct 2020 02:23:13
	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:23:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered 'No (N)'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:23:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c' User entered '25 Oct 2020 22:23:08'	System	26 Oct 2020 02:23:13
	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '25 Oct 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '29 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 99'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-01T19:05:09', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed582560-ad5a-4102-badd-d5a3bc1bf23f' User entered 'No (N)'	System	02 Nov 2020 00:05:24
	System	02 Nov 2020 00:05:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-01T19:05:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed582560-ad5a-4102-badd-d5a3bc1bf23f' User entered 'No (N)'	System	02 Nov 2020 00:05:24
	System	02 Nov 2020 00:05:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-01T19:05:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed582560-ad5a-4102-badd-d5a3bc1bf23f' User entered '01 Nov 2020 19:05:22'	System	02 Nov 2020 00:05:24
	System	02 Nov 2020 00:05:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '01 Nov 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '05 Nov 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 106'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-08T22:07:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0312886b-4ec9-4aad-ba14-e2d418bffb6f' User entered 'No (N)'	System	09 Nov 2020 03:07:44
	System	09 Nov 2020 03:07:44

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-08T22:07:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0312886b-4ec9-4aad-ba14-e2d418bffb6f' User entered 'No (N)'	System	09 Nov 2020 03:07:44
	System	09 Nov 2020 03:07:44

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-08T22:07:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0312886b-4ec9-4aad-ba14-e2d418bffb6f' User entered '08 Nov 2020 22:07:41'	System	09 Nov 2020 03:07:44
	System	09 Nov 2020 03:07:44

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '08 Nov 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '12 Nov 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 113'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-15T22:38:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0ba7a10a-4b74-4087-84b3-d0098186d870' User entered 'No (N)'	System	16 Nov 2020 03:38:53
	System	16 Nov 2020 03:38:53

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-15T22:38:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0ba7a10a-4b74-4087-84b3-d0098186d870' User entered 'No (N)'	System	16 Nov 2020 03:38:53

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-15T22:38:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0ba7a10a-4b74-4087-84b3-d0098186d870' User entered '15 Nov 2020 22:38:51'	System	16 Nov 2020 03:38:53
	System	16 Nov 2020 03:38:53

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '15 Nov 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:41:59
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '19 Nov 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-20T10:08:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3548a66b-1e35-4a55-ab9f-6d29796ab6a0' User entered 'No (N)'	System	20 Nov 2020 15:08:58
	System	20 Nov 2020 15:08:58

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-20T10:08:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3548a66b-1e35-4a55-ab9f-6d29796ab6a0' User entered 'No (N)'	System	20 Nov 2020 15:08:58

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-20T10:08:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3548a66b-1e35-4a55-ab9f-6d29796ab6a0' User entered '20 Nov 2020 10:08:55'	System	20 Nov 2020 15:08:58
	System	20 Nov 2020 15:08:58

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-26T09:21:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5db3422b-c6ff-4255-90f2-ea8b479c048f' User entered 'No (N)'	System	26 Nov 2020 14:21:43
	System	26 Nov 2020 14:21:43

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-26T09:21:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5db3422b-c6ff-4255-90f2-ea8b479c048f' User entered 'No (N)'	System	26 Nov 2020 14:21:43

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-26T09:21:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5db3422b-c6ff-4255-90f2-ea8b479c048f' User entered '26 Nov 2020 09:21:41'	System	26 Nov 2020 14:21:43
	System	26 Nov 2020 14:21:43

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-04T08:57:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f90f215e-d4d4-4dbe-8148-a93bf6971a6a'	System	04 Dec 2020 13:58:07
User entered 'No (N)'	System	04 Dec 2020 13:58:07

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-04T08:57:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f90f215e-d4d4-4dbe-8148-a93bf6971a6a'	System	04 Dec 2020 13:58:07
User entered 'No (N)'	System	04 Dec 2020 13:58:07

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-04T08:58:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f90f215e-d4d4-4dbe-8148-a93bf6971a6a' User entered '04 Dec 2020 08:58:02'	System	04 Dec 2020 13:58:07
	System	04 Dec 2020 13:58:07

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-10T09:06:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '09724e88-ad58-44c7-922f-dc89973b40ce' User entered 'No (N)'	System	10 Dec 2020 14:06:33
	System	10 Dec 2020 14:06:33

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-10T09:06:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '09724e88-ad58-44c7-922f-dc89973b40ce' User entered 'No (N)'	System	10 Dec 2020 14:06:33
	System	10 Dec 2020 14:06:33

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-10T09:06:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '09724e88-ad58-44c7-922f-dc89973b40ce' User entered '10 Dec 2020 09:06:28'	System	10 Dec 2020 14:06:33
	System	10 Dec 2020 14:06:33

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-17T08:26:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c486e5ca-6eb9-41c1-a39a-3b3139cbbe31' User entered 'No (N)'	System	17 Dec 2020 13:26:31
	System	17 Dec 2020 13:26:31

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-17T08:26:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c486e5ca-6eb9-41c1-a39a-3b3139cbbe31' User entered 'No (N)'	System	17 Dec 2020 13:26:31

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-17T08:26:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c486e5ca-6eb9-41c1-a39a-3b3139cbbe31' User entered '17 Dec 2020 08:26:29'	System	17 Dec 2020 13:26:31
	System	17 Dec 2020 13:26:31

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-24T08:41:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'dafe207b-b8c3-4fc6-9404-7eae392cb8b5'	System	24 Dec 2020 13:41:50
User entered 'No (N)'	System	24 Dec 2020 13:41:50

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-24T08:41:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'dafe207b-b8c3-4fc6-9404-7eae392cb8b5'	System	24 Dec 2020 13:41:50
User entered 'No (N)'	System	24 Dec 2020 13:41:50

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-24T08:41:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'dafe207b-b8c3-4fc6-9404-7eae392cb8b5' User entered '24 Dec 2020 08:41:42'	System	24 Dec 2020 13:41:50
	System	24 Dec 2020 13:41:50

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-31T08:07:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed9dbf0a-ba05-44fb-9a78-e51e3a77df80'	System	31 Dec 2020 13:08:10
User entered 'No (N)'	System	31 Dec 2020 13:08:10

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-31T08:08:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed9dbf0a-ba05-44fb-9a78-e51e3a77df80'	System	31 Dec 2020 13:08:10
User entered 'No (N)'	System	31 Dec 2020 13:08:10

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-12-31T08:08:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed9dbf0a-ba05-44fb-9a78-e51e3a77df80'	System	31 Dec 2020 13:08:10
User entered '31 Dec 2020 08:08:08'	System	31 Dec 2020 13:08:10

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-07T08:50:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '49e44285-7c55-470a-a767-0027b5c91f98'	System	15 Jan 2021 13:39:07
User entered 'No (N)'	System	15 Jan 2021 13:39:07

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-07T08:50:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '49e44285-7c55-470a-a767-0027b5c91f98'	System	15 Jan 2021 13:39:07
User entered 'No (N)'	System	15 Jan 2021 13:39:07

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-07T08:50:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '49e44285-7c55-470a-a767-0027b5c91f98' User entered '07 Jan 2021 08:50:27'	System	15 Jan 2021 13:39:07
	System	15 Jan 2021 13:39:07

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-15T08:38:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f2ba463-c7d7-48b6-b863-24dddd262b77'	System	15 Jan 2021 13:39:10
User entered 'No (N)'	System	15 Jan 2021 13:39:10

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-15T08:38:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f2ba463-c7d7-48b6-b863-24ddd262b77'	System	15 Jan 2021 13:39:10
User entered 'No (N)'	System	15 Jan 2021 13:39:10

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-15T08:39:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f2ba463-c7d7-48b6-b863-24dddd262b77'	System	15 Jan 2021 13:39:10
User entered '15 Jan 2021 08:39:04'	System	15 Jan 2021 13:39:10

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-21T09:59:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '914e1311-19e0-4ec3-8b8f-7fa920c995de' User entered 'No (N)'	System	21 Jan 2021 14:59:16
	System	21 Jan 2021 14:59:16

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-21T09:59:09', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '914e1311-19e0-4ec3-8b8f-7fa920c995de' User entered 'No (N)'	System	21 Jan 2021 14:59:16
	System	21 Jan 2021 14:59:16

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-21T09:59:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '914e1311-19e0-4ec3-8b8f-7fa920c995de' User entered '21 Jan 2021 09:59:14'	System	21 Jan 2021 14:59:16
	System	21 Jan 2021 14:59:16

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-28T07:58:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '760bbadf-e3bc-4a34-9341-6b55d25efb6d' User entered 'No (N)'	System	28 Jan 2021 12:59:05
	System	28 Jan 2021 12:59:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-28T07:58:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '760bbadf-e3bc-4a34-9341-6b55d25efb6d' User entered 'No (N)'	System	28 Jan 2021 12:59:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-01-28T07:59:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '760bbadf-e3bc-4a34-9341-6b55d25efb6d' User entered '28 Jan 2021 07:59:03'	System	28 Jan 2021 12:59:05
	System	28 Jan 2021 12:59:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-04T10:31:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7a6481a7-71c0-4968-8cf9-afd9bfff4018' User entered 'No (N)'	System	04 Feb 2021 15:32:05
	System	04 Feb 2021 15:32:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-04T10:31:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7a6481a7-71c0-4968-8cf9-afd9bfff4018' User entered 'No (N)'	System	04 Feb 2021 15:32:05
	System	04 Feb 2021 15:32:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-04T10:32:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7a6481a7-71c0-4968-8cf9-afd9bfff4018' User entered '04 Feb 2021 10:32:01'	System	04 Feb 2021 15:32:05
	System	04 Feb 2021 15:32:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-11T09:18:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b39eb7de-b330-4b69-8c98-8df65cbb565b' User entered 'No (N)'	System	11 Feb 2021 14:18:34
	System	11 Feb 2021 14:18:34

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-11T09:18:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b39eb7de-b330-4b69-8c98-8df65cbb565b' User entered 'No (N)'	System	11 Feb 2021 14:18:34

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-11T09:18:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b39eb7de-b330-4b69-8c98-8df65cbb565b' User entered '11 Feb 2021 09:18:32'	System	11 Feb 2021 14:18:34
	System	11 Feb 2021 14:18:34

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-18T10:29:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '737398ad-305d-4cf5-abdd-007a263e5d6b' User entered 'No (N)'	System	18 Feb 2021 15:29:28
	System	18 Feb 2021 15:29:28

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-18T10:29:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '737398ad-305d-4cf5-abdd-007a263e5d6b' User entered 'No (N)'	System	18 Feb 2021 15:29:28

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-18T10:29:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '737398ad-305d-4cf5-abdd-007a263e5d6b' User entered '18 Feb 2021 10:29:25'	System	18 Feb 2021 15:29:28
	System	18 Feb 2021 15:29:28

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-25T07:31:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c3d2ee10-4506-487d-a5bc-5e11328c0eb7' User entered 'No (N)'	System	01 Mar 2021 01:34:05
	System	01 Mar 2021 01:34:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-25T07:31:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c3d2ee10-4506-487d-a5bc-5e11328c0eb7'	System	01 Mar 2021 01:34:05
User entered 'No (N)'	System	01 Mar 2021 01:34:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-25T07:31:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c3d2ee10-4506-487d-a5bc-5e11328c0eb7' User entered '25 Feb 2021 07:31:42'	System	01 Mar 2021 01:34:05
	System	01 Mar 2021 01:34:05

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-04T08:15:13-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3a6475eb-898b-4bee-aa44-5948b2f8e0d6' User entered 'No (N)'	System	04 Mar 2021 13:15:28
	System	04 Mar 2021 13:15:28

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-04T08:15:16-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3a6475eb-898b-4bee-aa44-5948b2f8e0d6'	System	04 Mar 2021 13:15:28
User entered 'No (N)'	System	04 Mar 2021 13:15:28

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-04T08:15:24-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3a6475eb-898b-4bee-aa44-5948b2f8e0d6' User entered '04 Mar 2021 13:15:24'	System	04 Mar 2021 13:15:28
	System	04 Mar 2021 13:15:28

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-11T08:31:25-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '741290f6-617f-4ab3-a5b5-31ae9992c111'	System	11 Mar 2021 13:31:38
User entered 'No (N)'	System	11 Mar 2021 13:31:38

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-11T08:31:31-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '741290f6-617f-4ab3-a5b5-31ae9992c111'	System	11 Mar 2021 13:31:38
User entered 'No (N)'	System	11 Mar 2021 13:31:38

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-11T08:31:35-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '741290f6-617f-4ab3-a5b5-31ae9992c111'	System	11 Mar 2021 13:31:38
User entered '11 Mar 2021 08:31:35'	System	11 Mar 2021 13:31:38

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-18T09:11:33-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '22df2116-f499-4c09-af09-df4ba991529a' User entered 'No (N)'	System	18 Mar 2021 13:11:42
	System	18 Mar 2021 13:11:42

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-18T09:11:36-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '22df2116-f499-4c09-af09-df4ba991529a'	System	18 Mar 2021 13:11:42
User entered 'No (N)'	System	18 Mar 2021 13:11:42

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-18T09:11:40-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '22df2116-f499-4c09-af09-df4ba991529a' User entered '18 Mar 2021 09:11:40'	System	18 Mar 2021 13:11:42
	System	18 Mar 2021 13:11:42

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-25T09:29:39-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4338d0d0-81ef-4246-92c3-f29b4ddfc606'	System	25 Mar 2021 13:29:48
User entered 'No (N)'	System	25 Mar 2021 13:29:48

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-25T09:29:41-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4338d0d0-81ef-4246-92c3-f29b4ddfc606'	System	25 Mar 2021 13:29:48
User entered 'No (N)'	System	25 Mar 2021 13:29:48

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-03-25T09:29:45-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4338d0d0-81ef-4246-92c3-f29b4ddfc606'	System	25 Mar 2021 13:29:48
User entered '25 Mar 2021 09:29:45'	System	25 Mar 2021 13:29:48

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-01T07:20:39-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '787027c1-0f1d-4b3b-a144-77f69d87de56' User entered 'No (N)'	System	01 Apr 2021 11:20:59
	System	01 Apr 2021 11:20:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-01T07:20:42-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '787027c1-0f1d-4b3b-a144-77f69d87de56'	System	01 Apr 2021 11:20:59
User entered 'No (N)'	System	01 Apr 2021 11:20:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-01T07:20:55-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '787027c1-0f1d-4b3b-a144-77f69d87de56'	System	01 Apr 2021 11:20:59
User entered '01 Apr 2021 07:20:55'	System	01 Apr 2021 11:20:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-08T08:45:13-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '252c4b9d-25ba-4e12-9ccd-ec57557123e7' User entered 'No (N)'	System	08 Apr 2021 12:45:31

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-08T08:45:15-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '252c4b9d-25ba-4e12-9ccd-ec57557123e7'	System	08 Apr 2021 12:45:31
User entered 'No (N)'	System	08 Apr 2021 12:45:31

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-08T08:45:23-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '252c4b9d-25ba-4e12-9ccd-ec57557123e7'	System	08 Apr 2021 12:45:31
User entered '08 Apr 2021 08:45:23'	System	08 Apr 2021 12:45:31

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-15T10:12:37-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'a2e0700b-7d06-4c7f-b639-b3c58f54abd7'	System	15 Apr 2021 14:12:50
User entered 'No (N)'	System	15 Apr 2021 14:12:50

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-15T10:12:41-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'a2e0700b-7d06-4c7f-b639-b3c58f54abd7'	System	15 Apr 2021 14:12:50
User entered 'No (N)'	System	15 Apr 2021 14:12:50

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-15T10:12:45-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'a2e0700b-7d06-4c7f-b639-b3c58f54abd7' User entered '15 Apr 2021 10:12:45'	System	15 Apr 2021 14:12:50
	System	15 Apr 2021 14:12:50

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-22T11:31:39-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c2276c32-3e53-4350-88ee-ecbef60a09f4'	System	22 Apr 2021 15:31:48
User entered 'No (N)'	System	22 Apr 2021 15:31:48

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-22T11:31:41-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c2276c32-3e53-4350-88ee-ecbef60a09f4'	System	22 Apr 2021 15:31:48
User entered 'No (N)'	System	22 Apr 2021 15:31:48

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-22T11:31:44-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c2276c32-3e53-4350-88ee-ecbef60a09f4'	System	22 Apr 2021 15:31:48
User entered '22 Apr 2021 11:31:44'	System	22 Apr 2021 15:31:48

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-29T08:38:16-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '9d533048-b382-41b9-8ebd-e8d744f77cdf'	System	29 Apr 2021 12:38:26
User entered 'No (N)'	System	29 Apr 2021 12:38:26

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-29T08:38:18-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '9d533048-b382-41b9-8ebd-e8d744f77cdf'	System	29 Apr 2021 12:38:26
User entered 'No (N)'	System	29 Apr 2021 12:38:26

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-04-29T08:38:22-04:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '9d533048-b382-41b9-8ebd-e8d744f77cdf'	System	29 Apr 2021 12:38:26
User entered '29 Apr 2021 08:38:22'	System	29 Apr 2021 12:38:26

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:13:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-28T20:34:15-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '761cdb07-fe20-4318-bb7d-ed7f3678e4b9'	System	01 Mar 2021 01:34:33
User entered 'No (N)'	System	01 Mar 2021 01:34:33

US3402042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:13:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2021-02-28T20:34:27-05:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '761cdb07-fe20-4318-bb7d-ed7f3678e4b9'	System	01 Mar 2021 01:34:33
User entered '01 Mar 2021 01:34:27'	System	01 Mar 2021 01:34:33

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:11:09
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 21:35:49
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:11:09
User entered '19 Oct 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:11:09
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:11:09
User entered empty.	Traci Hull (b) (4)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:11:09
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 21:35:38
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:57:49
User entered 'I'	System	19 Oct 2020 21:35:38

US3402042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Nov 2020 15:15:13

US3402042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '25 Nov 2020'	(b) (4) Traci Hull (b) (4)	25 Nov 2020 15:15:13

US3402042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	25 Nov 2020 15:15:13

US3402042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4)	25 Nov 2020 15:15:13
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4)	25 Nov 2020 15:15:03
	Traci Hull (b) (4)	
	(b) (4)	

US3402042

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User entered 'I'	System	25 Nov 2020 15:15:03

US3402042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Dec 2020 15:52:53

US3402042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '23 Dec 2020'	(b) (4) Tammy Kohn (b) (4)	24 Dec 2020 15:52:53

US3402042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	24 Dec 2020 15:52:53

US3402042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Dec 2020 15:52:53
	(b) (4)	

US3402042

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Dec 2020 15:52:57

US3402042

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User entered 'I'	System	24 Dec 2020 15:52:57

US3402042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	25 Jan 2021 16:41:54

US3402042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '19 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	25 Jan 2021 16:41:54

US3402042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	25 Jan 2021 16:41:54

US3402042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	25 Jan 2021 16:41:54
	(b) (4)	

US3402042

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	25 Jan 2021 16:41:59

US3402042

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:17:12
User entered 'I'	System	25 Jan 2021 16:41:59

US3402042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Feb 2021 19:06:25

US3402042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '18 Feb 2021'	(b) (4) Tammy Kohn (b) (4)	18 Feb 2021 19:06:25

US3402042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 19:06:25

US3402042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User entered 'VISIT4'	System	18 Feb 2021 19:06:25

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User entered empty.	System	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User entered empty.	System	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User entered empty.	System	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User entered empty.	System	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User entered empty.	System	31 Mar 2021 18:51:37

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31

US3402042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31

US3402042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	18 Feb 2021 19:07:00

US3402042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	(b) (4) Tammy Kohn (b) (4)	18 Feb 2021 19:07:00

US3402042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Abigail Wine (b) (4)	18 Mar 2021 15:58:27

US3402042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '18 Feb 2021'	(b) (4) Abigail Wine (b) (4)	18 Mar 2021 15:58:27

US3402042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '12:57'	(b) (4) Abigail Wine (b) (4)	18 Mar 2021 15:58:27

US3402042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered '18 Feb 2021 12:57'	System	18 Mar 2021 15:58:27

US3402042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Feb 2021 19:07:05

US3402042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:18:33
User entered 'I'	System	18 Feb 2021 19:07:05

US3402042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	Traci Hull (b) (4)	22 Mar 2021 20:22:38

US3402042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered '22 Mar 2021'	Traci Hull (b) (4)	22 Mar 2021 20:22:38

US3402042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	22 Mar 2021 20:22:38

US3402042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered empty.	Traci Hull (b) (4)	22 Mar 2021 20:22:38

US3402042

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Yes (Y)'	Traci Hull (b) (4)	22 Mar 2021 20:22:42

US3402042

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:08
User entered 'I'	System	22 Mar 2021 20:22:42

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:35

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:24
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:53:15
User closed query 'Please review CCG V2.0 and use the "Add Event" function to add the illness folder. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:59:38
Query 'Please review CCG V2.0 and use the "Add Event" function to add the illness folder. ' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 13:18:01
User opened query 'Please review CCG V2.0 and use the "Add Event" function to add the illness folder. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:59:53
User closed query 'Subject has covid assessment done but no Illness or Convalescent visit. Please confirm if there was an illness visit and convalescent follow up done. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:59:53
Query 'Subject has covid assessment done but no Illness or Convalescent visit. Please confirm if there was an illness visit and convalescent follow up done. ' answered with 'ILLNESS VISIT WAS DONE-NO ILLNESS VISIT PAGE IS GENERATING' (Site from CRA).	Abigail Wine (b) (4) (b) (4)	29 Oct 2020 22:55:06
User opened query 'Subject has covid assessment done but no Illness or Convalescent visit. Please confirm if there was an illness visit and convalescent follow up done. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:01:35
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:35

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:24
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:53:18
User entered '14:00'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:35

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:24
User entered '12 Oct 2020 14:00'	System	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:35

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:24
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:53:19
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:35

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:24
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:53:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 1 (Day 1)'	(b) (4) Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User closed query 'Per source, please update date to 12-OCT-2020.' (Site from CRA).	(b) (4)	
Query 'Per source, please update date to 12-OCT-2020.' answered with 'SUBJECTS SYMPTOMS BEGAN ON 01OCT2020.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:54:31
User opened query 'Per source, please update date to 12-OCT-2020.' (Site from CRA).	Tammy Kohn (b) (4)	17 Apr 2021 12:42:26
DataPoint Verified.	(b) (4)	
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (12OCT2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 19:26:46
Query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (12OCT2020) or update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '01 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (12OCT2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:25:13
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 23:10:22
	(b) (4)	
	Jennifer Molstead (b) (4)	09 Nov 2020 23:10:11
	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 03:58:06
	Traci Hull (b) (4)	13 Oct 2020 13:08:37
	(b) (4)	

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered '1' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '0'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '93'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:37:16
User entered '%'	System	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '96.3' F	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint activated with code reason code Data required.	(b) (4)	
	Tammy Kohn (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Traci Hull (b) (4)	14 Oct 2020 14:40:14
User entered 'Day 2 (Day 2)'	(b) (4)	
	Traci Hull (b) (4)	14 Oct 2020 14:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '02 Oct 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:40:14
User entered '13 Oct 2020'	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:38:51

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:40:14
User entered '0'	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:38:51

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:37:16
DataPoint activated with code reason code Data required.	(b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	14 Oct 2020 14:40:14
User entered '90'	Traci Hull (b) (4)	14 Oct 2020 14:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:37:16
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	14 Oct 2020 14:40:14
User entered '%'	Traci Hull (b) (4)	14 Oct 2020 14:38:51
	System	

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Folder: Covid-19 Assessment 12 Oct 2020

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Apr 2021 12:37:16
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:37:16
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Oct 2020 14:38:51
User entered '97.' (non-conformant).	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

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Form: Symptom Log (2)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

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Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:14
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:38:51

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	17 Apr 2021 12:35:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:40:14
User entered empty.	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:38:51

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 2 (Day 2)'	(b) (4) Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '13 Oct 2020'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered '1' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '0'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '90'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31
User entered '%'	System	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '97.3' F	Traci Hull (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 3 (Day 3)'	(b) (4) Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User closed query 'Per source please update date to 14-OCT-2020.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:54:57
Query 'Per source please update date to 14-OCT-2020.' answered with 'SUBJECTS SYMPTOMS BEGAN ON 01OCT2020' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:42:52
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31
User entered '04 Oct 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31
User opened query 'Per source please update date to 14-OCT-2020.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:27:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User closed query 'Subject hasn't entered symptom log for 13Oct20 - 16Oct20, and days following 16Oct20. Subject still appears to have mild cough, nasal congestion, and runny nose reported as of 16Oct20' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 01:01:07
Query 'Subject hasn't entered symptom log for 13Oct20 - 16Oct20, and days following 16Oct20. Subject still appears to have mild cough, nasal congestion, and runny nose reported as of 16Oct20' answered with 'Subject swab result were negative. Subject was taken out of illness phase' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:30:08
User opened query 'Subject hasn't entered symptom log for 13Oct20 - 16Oct20, and days following 16Oct20. Subject still appears to have mild cough, nasal congestion, and runny nose reported as of 16Oct20' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:04:01
User entered '16 Oct 2020'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered '1' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '90'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31
User entered '%'	System	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered '97.7' F	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
DataPoint Un-verified.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
User entered empty; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:13
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 4 (Day 4)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '05 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'I'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 5 (Day 5)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	17 Apr 2021 12:41:48
User entered '06 Oct 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:48
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	17 Apr 2021 12:41:31
User entered '06 Oct 2021'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'I'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 6 (Day 6)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '07 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'l'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 7 (Day 7)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '08 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'l'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '09 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'l'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

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Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 9 (Day 9)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	20 Apr 2021 14:56:39
User entered '10 Oct 2020'	Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'l'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 10 (Day 10)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '11 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'l'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 11 (Day 11)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '12 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '0' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:47:35
User entered '1'	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '93' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered '%'	System	17 Apr 2021 12:44:45
User entered empty.	System	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '96.3' F reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Apr 2021 12:44:45
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:41:31

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 12 (Day 12)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '13 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '0'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '90'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered '%'	System	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '97.3' F	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:47:35

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
User entered 'Day 13 (Day 13)'	(b) (4) Tammy Kohn (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '14 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '0'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '90'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User entered '%'	System	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered '97.7' F	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:56:39
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 12:49:04

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:46
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:35

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User entered '0'	System	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:24:35

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:27:50
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	11 Dec 2020 13:10:28

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:22:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:51:09

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:18:51
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:18:51
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 10:48:17
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:18:51
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User entered 'SICKD1'	System	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	16 Apr 2021 19:19:46
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:46
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	16 Apr 2021 19:19:46
User entered '14:19'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User entered '12 Oct 2020 14:19'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
DataPoint set to visible.	(b) (4)	System
		30 Oct 2020 10:48:17

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:19:46
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
DataPoint set to visible.	(b) (4) System	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:19:46
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 11:15:07
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:32
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Oct 2020 10:49:11
User entered '96.3' F	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:19:46
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	16 Apr 2021 19:19:46
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:19:46
User entered '73'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User entered 'bpm'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '18'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User entered 'breaths/min'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:19:46
User closed query 'Per CDM: Per previous responses, Systolic and Diastolic Blood Pressure results were Clinically Significant however there is no corresponding Adverse Event recorded. Please review and reconcile data or explain.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:51:42
Query 'Per CDM: Per previous responses, Systolic and Diastolic Blood Pressure results were Clinically Significant however there is no corresponding Adverse Event recorded. Please review and reconcile data or explain.' answered with 'CORRECT AS IS. SUBJECT SENT TO EMERGENCY ROOM.' (Site from DM).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:46:10
User entered '150' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:43:07
User opened query 'Per CDM: Per previous responses, Systolic and Diastolic Blood Pressure results were Clinically Significant however there is no corresponding Adverse Event recorded. Please review and reconcile data or explain.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:18:46
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 11:15:14
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject was advised to go to the emergency room CS' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:50:03
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Oct 2020 10:49:11
User entered '74'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User entered 'mmHg'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:19:46
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:51:45
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS IS. SUBJECT WAS SENT TO EMERGENCY ROOM.' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:46:28
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		03 Nov 2020 15:43:07
User entered '58' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:43:07
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 11:15:15
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject was advised to go to the emergency room CS' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:50:05
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Oct 2020 10:49:11
User entered '54'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User entered 'mmHg'	System	30 Oct 2020 10:49:11

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:50:28
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:56
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 10:50:28

US3402042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:35

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:20:14
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:50:40

US3402042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:20:14
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:50:40

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Jan 2021 20:17:28
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '21 Jan 2021'	Traci Hull (b) (4)	21 Jan 2021 20:17:28
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	21 Jan 2021 20:17:28
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 20:17:28

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '06 Jan 2021'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	08 Apr 2021 15:38:17
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:39:44

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:44:22
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	08 Apr 2021 15:38:36
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Traci Hull (b) (4)	08 Apr 2021 15:38:17
	(b) (4)	
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:18:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:39:44

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '21 Jan 2021'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	21 Jan 2021 20:18:02
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User entered empty.	System	21 Jan 2021 20:18:02

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User entered empty.	System	21 Jan 2021 20:18:02

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Jan 2021 20:18:14
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '21 Jan 2021'	Traci Hull (b) (4)	21 Jan 2021 20:18:14
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '13:49'	Traci Hull (b) (4)	21 Jan 2021 20:18:14
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User entered '21 Jan 2021 13:49'	System	21 Jan 2021 20:18:14

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Jan 2021 20:18:27
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:35

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '21 Jan 2021'	Traci Hull (b) (4)	21 Jan 2021 20:18:27
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
	(b) (4)	
User entered '13:50'	Traci Hull (b) (4)	21 Jan 2021 20:18:27
	(b) (4)	

US3402042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:31:52
User entered '21 Jan 2021 13:50'	System	21 Jan 2021 20:18:27

US3402042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:24:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:32
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:38
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:31:04
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 14:38:32

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 22:10:34
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 22:10:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:43:09
User entered	System	14 Oct 2020 13:43:03
'USA-US059-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 13:43:03

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:21:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:21:45
Data point term sent to Coder	System	07 Oct 2020 13:33:53
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:48:58
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:12:45
User entered '01 Oct 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '1 Oct 2020'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:12:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:41:41
User entered '17 Oct 2020' reason for change: Per Query Resolution	(b) (4)	29 Oct 2020 22:40:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:32:02
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	13 Oct 2020 22:01:40
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 08:29:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still inpatient. ' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	13 Oct 2020 22:02:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 22:01:40
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	13 Oct 2020 22:01:40
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '13 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:01:40
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:12:43
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:41:47
	(b) (4)	
User entered '17 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:32:42
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:02:16
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Not Applicable (NOT APPLICABLE)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'I'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:12:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:41:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:33:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Traci Hull (b) (4)	07 Oct 2020 13:33:02

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:30:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'Per DM CLR: SAE Narrative indicates Oxygen and Azithromycin were given. However, there is no corresponding ConMed record that match these medication. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:16:21
User closed query 'PV Query: Please report if there was any trigger for the worsening of emphysema (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:13:07
User closed query 'PV Query: It was noted that the subject was treated with azithromycin. Please update the treatment medications to reflect the details (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:13:03
User closed query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:11:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:11:39
Query 'Per DM CLR: SAE Narrative indicates Oxygen and Azithromycin were given. However, there is no corresponding ConMed record that match these medication. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:49:52
Query 'PV Query: Please report if there was any trigger for the worsening of emphysema (ie. infection, medication noncompliance, etc.).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:49:44
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'None provided' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:49:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject began with congestion 01OCT2020 Went to his pulmonologist and was started on prednisone and Cefdir. SUBJECT CAME FOR ILLNESS VISIT 12OCT2020. AFTER HAVING PHYSICAL EXAM IT WAS DETERMINED BY SUB INVESTIGATOR THAT SUBJECT SHOULD GO THE THE EMERGENCY ROOM FOR FURTHER EVALUATION. SUBJECT WAS LATER ADMITTED TO HOSPITAL FOR FURTHER TREATMENT. SUBJCT HAD CHEST XRAY WHICH SHOWED CHANGES IN BTH LUNGS PARTICULARLY WITH IN THE UPPER LOBES WITH LINEAR SCARRING WITH IN THE MID AND LOWER LUNG ZONES AS NOTED ON PREIOUS STUDIES. SUBJECT IS ON 3L OF OXYGEN BY NASAL CANNULA. SUBJECT WILL CONTINUE ON CEFTRIAXONE, AND AZITHROMYCIN,. WILL BE STARTED ON METHYLPREDNISOLONE.' reason for change: New Information	Jennifer Molstead (b) (4)	(b) (4) 29 Oct 2020 22:49:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid test preformed' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 29 Oct 2020 22:44:04
Query 'PV Query: It was noted that the subject was treated with azithromycin. Please update the treatment medications to reflect the details (including dates of administration, dose, units, frequency, route and indication).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 29 Oct 2020 22:42:41
User opened query 'Per DM CLR: SAE Narrative indicates Oxygen and Azithromycin were given. However, there is no corresponding ConMed record that match these medication. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:00:21
User opened query 'PV Query: Please report if there was any trigger for the worsening of emphysema (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:35:26

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:34:25
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:34:05
User opened query 'PV Query: It was noted that the subject was treated with azithromycin. Please update the treatment medications to reflect the details (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:33:47
User entered 'SUBJECT CAME FOR ILLNESS VISIT 12OCT2020. AFTER HAVING PHYSICAL EXAM IT WAS DETERMINED BY SUB INVESTIGATOR THAT SUBJECT SHOULD GO THE THE EMERGENCY ROOM FOR FURTHER EVALUATION. SUBJECT WAS LATER ADMITTED TO HOSPITAL FOR FURTHER TREATMENT. SUBJCT HAD CHEST XRAY WHICH SHOWED CHANGES IN BTH LUNGS PARTICULARLY WITH IN THE UPPER LOBES WITH LINEAR SCARRING WITH IN THE MID AND LOWER LUNG ZONES AS NOTED ON PREIOUS STUDIES. SUBJECT IS ON 3L OF OXYGEN BY NASAL CANNULA. SUBJECT WILL CONTINUE ON CEFTRIAXONE, AND AZITHROMYCIN,. WILL BE STARTED ON METHYLPREDNISOLONE.' reason for change: New Information	Jennifer Molstead (b) (4)	18 Oct 2020 14:20:53
User entered 'Subject came for Illness visit 12Oct2020. After having physical exam it was determined by Sub investigator that subject should go the the emergency room for further evaluation. Subject was later admitted to hospital for further treatment.' reason for change: New Information	Jennifer Molstead (b) (4)	13 Oct 2020 22:01:40
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:01:40
User entered '0'	System	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:33:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 22:02:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:24:35

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:20:56
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:58:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:01:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:01:45
Data point term sent to Coder	System	26 Sep 2020 14:00:37
User entered 'ELIQUIS'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'DEEP VEIN THROMBOSIS/ PULMINARY EMBOLISM'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:59:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:59:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:59:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2018'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:59:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:59:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 10:35:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 10:35:44
Data point term sent to Coder	System	26 Sep 2020 14:01:37
User entered 'TOMSULOSIN'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:20:11
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'CORRECT AS IS.' (Site from DM).	Traci Hull (b) (4)	05 Oct 2020 16:00:39
User entered '.04' reason for change: Per Query Resolution	(b) (4)	05 Oct 2020 16:00:29
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:45:47
User entered '0.04'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 1992'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:04:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:04:46
Data point term sent to Coder	System	26 Sep 2020 14:03:38
User entered 'FLUOXETINE'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'DEPRESSION'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '40'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2012'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:05:47
Data point term sent to Coder	System	26 Sep 2020 14:04:40
User entered 'BISOPROLOL'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'HYPERTENSION'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2000'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:47
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
User entered '17 Oct 2020' reason for change: New Information	(b) (4)	
	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User entered '1'	System	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User entered '1'	System	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:32
User entered '804 (804)'	System	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:06:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:06:47
	(b) (4)	
Data point term sent to Coder	System	26 Sep 2020 14:05:40
User entered 'HYDROCHLORATHIAZIDE'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'HYPERTENSION'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '6.25'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2000'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:07:47
Data point term sent to Coder	System	26 Sep 2020 14:06:41
User entered 'OMEPRAZOLE'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	(b) (4), (b) (6)	06 Oct 2020 10:21:24
' (Site from DM).		
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Traci Hull (b) (4)	05 Oct 2020 16:03:02
	(b) (4)	
' answered with 'MED HISTORY UPDATED TO REFLECT GASTROESOPHAGEAL REFLUX DISEASE' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	(b) (4), (b) (6)	05 Oct 2020 07:48:31
' (Site from DM).		
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '40'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 1990'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: ROFLUMILAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 10:57:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 10:57:40
Data point term sent to Coder	System	26 Sep 2020 14:08:41
User entered 'ROFLUMILAST'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'EMPHYSEMA'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:21:33
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	05 Oct 2020 16:07:48
User entered '250' reason for change: New Information	(b) (4)	05 Oct 2020 16:07:33
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:48:48
User entered '40'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'ug (ug)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:07:33
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2016'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE, PRODUCTSYNONYM: BEVESPI AEROSPHERE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:11:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:11:47
Data point term sent to Coder	System	26 Sep 2020 14:10:42
User entered 'BEVESPI AEROSPHERE'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'EMPHYSEMA'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '9/4.8'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'ug (ug)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2018'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:37:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:37:16
Data point term sent to Coder	System	05 Oct 2020 16:10:05
User entered 'DOXYCYCLINE'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '100'	Traci Hull (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '1 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4)	13 Oct 2020 14:59:14
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	13 Oct 2020 14:59:14
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	06 Nov 2020 04:22:42
User entered 'No (N)'	(b) (4), (b) (6)	
	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User entered '2'	System	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User entered '1'	System	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:41
User entered '804 (804)'	System	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
Data point term sent to Coder	System	05 Oct 2020 16:14:12
User entered 'PREDNISONE'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '30'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '01 Oct 2020'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '4 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User entered '1'	System	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User entered '1'	System	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:46
User entered '804 (804)'	System	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
Data point term sent to Coder	System	05 Oct 2020 16:15:14
User entered 'PREDNISONE'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '25'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5 Oct 2020'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	06 Oct 2020 15:12:49
User entered '6 Oct 2020' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	06 Oct 2020 15:12:49
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	05 Oct 2020 16:14:33
User entered '06 Oct 2020'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User entered '1'	System	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User entered '1'	System	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:13
User entered '804 (804)'	System	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:07:29
Data point term sent to Coder	System	09 Oct 2020 15:29:53
User entered 'PREDNISONEE'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '20'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '7 Oct 2020'	Traci Hull (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '8 Oct 2020'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User entered '1'	System	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User entered '1'	System	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:16
User entered '804 (804)'	System	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:01:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:01:29
Data point term sent to Coder	System	13 Oct 2020 15:00:49
User entered 'PREDNISONE'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '15'	Traci Hull (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4)	13 Oct 2020 15:00:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '9 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '10 Oct 2020'	Traci Hull (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User entered '1'	System	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User entered '1'	System	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:20
User entered '804 (804)'	System	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 14:32:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 14:32:20
Data point term sent to Coder	System	18 Oct 2020 14:23:14
User entered 'APIXABAN'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING EMPHYSEMA'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:46:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:46:25
Data point term sent to Coder	System	18 Oct 2020 14:26:17
User entered 'CEFTRIAXONE'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING EMPHYSEMA'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'l'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'g (g)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Oct 2020 11:44:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Oct 2020 11:44:09
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Oct 2020 14:25:18
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per CDM : If not Ongoing, End date (dd MMM yyyy is updated however the Ongoing field is left blank. Kindly update as appropriate else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:52:35
Query 'Per CDM : If not Ongoing, End date (dd MMM yyyy is updated however the Ongoing field is left blank. Kindly update as appropriate else clarify in query response.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Nov 2020 18:37:04
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	04 Nov 2020 18:36:57
User opened query 'Per CDM : If not Ongoing, End date (dd MMM yyyy is updated however the Ongoing field is left blank. Kindly update as appropriate else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 04:10:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 11:45:48
Query 'Data is required. Please complete.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4) (b) (4)	19 Oct 2020 11:44:43
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Oct 2020 14:25:18
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User entered '1'	System	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User entered '1'	System	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:38
User entered '804 (804)'	System	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:47:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:47:25
Data point term sent to Coder	System	18 Oct 2020 14:29:18
User entered 'METHYLPREDNISOLONE'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING EMPHYSEMA'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '40'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 21:38:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 21:38:34
Data point term sent to Coder	System	19 Oct 2020 21:37:52
User entered 'CEFDINIR'	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'PNEUMONIA'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '300'	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '17 Oct 2020'	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:29:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:29:51
Data point term sent to Coder	System	29 Oct 2020 22:52:05
User entered 'Oxygen'	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Worsening Emphysema'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '3'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Liters'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	06 Nov 2020 04:22:42
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'continous'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Nasal (NASAL)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '17 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User entered empty.	System	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User entered empty.	System	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:57
User entered empty.	System	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:34:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:34:46
Data point term sent to Coder	System	29 Oct 2020 22:53:06
User entered 'Azithromycin'	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Worsening Emphysema'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '500'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '17 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User entered '1'	System	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User entered '1'	System	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:00
User entered '804 (804)'	System	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:24:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	Jennifer Molstead (b) (4) 18 Oct 2020 14:13:57
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 14:39:03
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:11
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:14:26

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:11
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
User entered 'CHEST XRAY'	Jennifer Molstead (b) (4)	18 Oct 2020 14:14:26

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:11
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:14:26

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:35

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:11
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:21:19
User entered empty.	(b) (4)	Jennifer Molstead (b) (4) 18 Oct 2020 14:14:26
	(b) (4)	

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered	System	14 Oct 2020 13:43:03
'USA-US059-2020-MRNA-1273-P301000006'		

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered	System	14 Oct 2020 13:43:03
'USA-US059-2020-MRNA-1273-P301000006'		

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '14/Oct/2020 13:44'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered		
'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '19/Oct/2020 16:55'	System	19 Oct 2020 16:55:04

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:56:39
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 16:55:04

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered	System	14 Oct 2020 13:43:03
'USA-US059-2020-MRNA-1273-P301000006'		

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:24:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '30/Oct/2020 15:16'	System	30 Oct 2020 15:16:32

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:24:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 14:17:59
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 15:16:32

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered		
'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:24:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:25:20
User entered '12/Nov/2020 14:18'	System	12 Nov 2020 14:18:12

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:24:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:22:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:25:22
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 14:18:12